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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/981,583 02/03/98 DICKMANNS

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EXAMINER

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HARRIS, A

ART UNIT	PAPER NUMBER
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1642

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DATE MAILED:

08/28/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/981,583	Applicant(s) Dickmanns et al.
	Examiner Alana M. Harris, Ph. D.	Group Art Unit 1642

Responsive to communication(s) filed on May 17 and May 26, 2000.

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle* 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

Claim(s) 1-12, 16-22, 29-31, 33-35, and 38 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 1-12, 16-22, 29-31, 33-35, and 38 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- Notice of References Cited, PTO-892
- Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- Interview Summary, PTO-413
- Notice of Draftsperson's Patent Drawing Review, PTO-948
- Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

Response to Amendment

1. Claims 13-15, 32, 36 and 37 have been canceled.

Claims 38 has been added.

Claims 6, 7, 32 and 34 have been amended.

Claims 1-12, 16-22, 29-31, 33-35 and 38 are pending.

Claims 1-12, 16-22, 29-31, 33-35 and 38 are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Priority

3. This application, filed under former 37 CFR 1.60 now has the necessary reference to prior applications.

Specification

4. The objection to disclosure because of the following informality: the brief description of the figures lack a separate brief description: Figure 4a, Figure 4b, Figure 4c, Figure 5a and Figure 5b is withdrawn.

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5. The rejection of claims 33 and 34 under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement commensurate with the scope of the claimed invention is withdrawn in view of Applicants' amendment to the claims.

6. The rejection of claims 7, 12, 29 and 33-35 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

Claim Rejections - 35 U.S.C. § 112

7. The rejection of claim 35 is under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement commensurate with the scope of the claimed invention is maintained. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Applicants state they "do not agree with the Examiner's basis for this rejection" and point out that on pages 14 and 15 of the specification pharmaceutical composition which comprises the claimed subject matter is clearly described. Applicants' did amend claims 33 and 34 in order to obviate the rejection, however claim 35 still recites the language at issue.

Claim 35 is broadly drawn to "a pharmaceutical composition comprising the epithelial tumor cell". The specification while being enabling for a composition comprising an epithelial

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tumor cell of claim 1 and a pharmaceutically acceptable carrier, does not reasonably provide enablement for a “pharmaceutical composition” comprising these same components. Claims drawn to “pharmaceutical compositions” are broadly interpreted to read on compositions effective for use as *in vivo* human therapeutics, hence the rejection is maintained for reasons set forth in Paper No. 15, mailed February 17, 2000. The applicant is advised to amend the claim to delete the first recitation of “pharmaceutical”.

Claim Rejections - 35 U.S.C. § 102

8. The rejection of claims 1-3, 6-10, 16-19, 21 and 22 and newly added claim 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Garcia et al. (Molecular and Cellular Biology 6(6):1974-1982) is made and maintained. Applicants argue that Garcia et al. “actually discloses an immortalized epithelial after transformation was tumorigenic, but had no metastatic potential. Furthermore, the transformed original cell was a primary rabbit mammary secretory cell, i.e., a normal tissue cell and not a tumor cell as recited in claim 1...”. Hence, Applicants argue that Garcia describes the transformation of normal epithelial cells and not of tumor of cells. This is not found persuasive. The claimed subject matter is a product, being an immortalized epithelial tumor cell with metastatic potential which has integrated in its genome or another replicative genetic element an externally introduce immortalizing oncogene which is expressed in said cell *and not the method by which the claimed subject matter is made*. Garcia et al. indeed discloses an autologous, disseminated immortalized rabbit mammary epithelial tumor cell with metastatic

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potential which has integrated in its genome or another replicative genetic element the DNA encoding the early region (large T antigen) of non-infectious SV40 DNA, claims 1-3, 6, 8 and 38. The epithelial tumor cell contains at least one defect in the origin of replication, claim 7.

Garcia et al. also disclose that the epithelial tumor cell has integrated in its genome at least one additional oncogene, wherein additional oncogene is c-Ha-ras, the same as that claimed (claims 9 and 10). The *in vitro* process by which the tumor cell incorporated the DNA encoding at least one immortalizing oncogene into a non-immortalized epithelial tumor cell with metastatic potential is disclosed by Garcia et al., claim 16. The step of incorporating DNA comprised microinjection, which was performed after the step of carrying out a primary expansion of said non-immortalized epithelial tumor cells, claims 17 and 18. The primary expansion comprised the step of culturing in a medium comprising epidermal growth factor on the extracellular matrix, collagen coated tissue flasks, the same as that claimed (claims 19, 21 and 22).

Claim Rejections - 35 U.S.C. § 103

9. The rejection of claims 1, 4, 5 and 16-20 under 35 U.S.C. 103(a) as being unpatentable over Garcia et al.(Molecular and Cellular Biology 6(6):1974-1982), in view of Schlimok et al. and Yanagihara et al. is maintained based on the reasons stated in the above paragraph.

10. The rejection of claims 1, 11, 12, 16, 29 and 30 under 35 U.S.C. 103(a) as being unpatentable over Garcia et al.(Molecular and Cellular Biology 6(6):1974-1982), in view of

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Blankenstein et al. (Current Biology 3:694-698, 1991) is maintained based on the reasons stated in Paragraph #8.

11. The rejection of claims 1, 16-19, 21 and 31 under 35 U.S.C. 103(a) as being unpatentable over Garcia et al.(Molecular and Cellular Biology 6(6):1974-1982), in view of Sigma Cell Culture Catalogue and Price List (1995) is maintained based on the reasons stated in above paragraphs.

12. The rejection of claims 1, 33 and 34 under 35 U.S.C. 103(a) as being unpatentable over Garcia et al.(Molecular and Cellular Biology 6(6):1974-1982), in view of Gottlinger et al. (Int. J. Cancer 38:47-53, 1986) is maintained based on the reasons stated in above paragraphs.

13. Applicant's amendments necessitated the new grounds of rejection presented in this office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expired THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

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will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (703) 306-5880. The examiner can normally be reached on Monday through Friday from 6:30 am to 3:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D., can be reached on (703)308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703)308-0196.

Alana M. Harris, Ph.D.
Patent Examiner, Group 1642
August 25, 2000


GEETHA P. BANSAL
PRIMARY EXAMINER